REMARKS/ARGUMENTS

Claims 13, 24-30, 40 and 41 are pending. Claims 13, 24-30, and 41 are withdrawn. Claim 40 is rejected.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claim 40 is rejected under 35 U.S.C. § 112, first paragraph, as not describing and enabling the invention. Applicants respectfully disagree.

The Examiner finds that the only utility for the compound where E=H is as an intermediate in preparing targeted compounds (i.e., where E=targeting agent). Applicants respectfully disagree.

On page 7, beginning at line 3, applicants disclose a method of performing a therapeutic procedure using the inventive organic azide dye where E is either H or a receptor binding molecule.

In addition, on page 10, beginning at line 12, applicants disclose that the inventive organic azide dye where E=a receptor binding molecule is only one embodiment of the invention ("In one embodiment, azides according to the present invention have the general formula 1 above wherein ... E is selected from the group consisting of somatostatin receptor binding molecules, heat sensitive bacterioendotoxin (ST) receptor binding molecules, neurotensin receptor binding molecules, bombesin receptor binding molecules, cholecystekinin (CCK) receptor binding molecules, steroid receptor binding molecules, and carbohydrate receptor binding molecules).

Applicants further disclose on page 13, beginning at line 22, that "For targeting purposes, external attachment of an epitope is used. If the aromatic azido

compounds themselves preferentially accumulate in th target tissue, however, an additional binding group may not be needed." This refutes the Examiner's assertion that the inventive organic azide dye when E=H is not a pharmaceutical composition, and its only purpose is as an intermediate.

For at least these reasons, applicants respectfully request that the rejection be withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

Claim 40 is rejected under 35 U.S.C. § 102(b) as anticipated by each of Pochinok, Ol'shevskaya, Clecak, and Leung. Applicants respectfully disagree.

Applicants note for the record that the invention relates to novel dye-azide compounds useful for dual phototherapeutic procedures and these phototherapeutic procedures using the inventive compounds. This is stated at the outset in characterizing the invention ("The present invention relates generally to novel compounds useful for dual phototherapeutic procedures and particularly to phototherapeutic procedures using dye-azide compounds"; Field of the Invention, page 1, emphasis added).

The Examiner's statement, then, that the arguments in the Amendment dated April 14, 2003 which included the Rajagopalan's Declaration are directed to the method, rather than the composition, are respectfully disputed. Dr. Rajagopalan makes a specific point of distinguishing compounds in a solvent, as disclosed in the cited references, from the claimed "pharmaceutically acceptable formulation". He is thus indeed directing his remarks to the composition.

Applicants assert the following in the Amendment and Declaration: that the inventive composition is a pharmaceutical formulation, that a compound in a solvent does not become a pharmaceutical formulation simply because it is dissolved in a solvent that applicants may use, and hence that applicants' composition is not disclosed in the prior art.

The Examiner notes that anticipatory prior art need only disclose the composition per se, not the same intended use. However, the prior art composition must be enabled. *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 65 U.S.P.Q.2d 1385 (Fed. Cir. 2003) ("In patent prosecution the examiner is entitled to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether or not that patent is enabled... The applicant, however, can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled").

Applicants respectfully assert that none of Pochinok, Ol'shevskaya, Clecak, and Leung enable the claimed pharmaceutically acceptable formulation of E – L – DYE – X – N_3. Pochinok only describes "dye in solutions" for *in vitro* photodecomposition studies. Ol'shevskaya and Clecak use ethanol as a reaction medium for the *in vitro* synthesis and reactions of the dyes. Leung discloses a dye dissolved in DMSO, a lower alcohol or another completely water-miscible solvent in which cells are incubated *in vitro*.

Applicants further respectfully assert that one skilled in the art, based upon these references, would not be able to prepare a pharmaceutically acceptable formulation that is administered to a patient absent undue experimentation (e.g., the

need for bioavailability, chemical stability, and physical stability, as stated at paragraph 5, page 2, of the Rajagopalan Declaration).

For at least these reasons, applicants respectfully assert that the rejection is improper and request that the rejection be withdrawn.

CONCLUSION

For the foregoing reasons, applicants submit that claim 40 is patentable and a Notice of Allowance is respectfully requested.

Applicants do not believe that any fees are due in connection with this Amendment. However, should any additional fees or surcharges be deemed necessary, the Examiner has authorization to charge fees or credit any overpayment to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

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